Medicines & Healthcare products
Regulatory Agency

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[redacted]

[redacted]

02 May 2023

FOI 23/027

Dear [redacted]

We apologise for the delay while handling your request.

In your information request, dated 12 January 2023, you asked for:

> "It has now been over 2 years since the rollout of covid vaccines in the UK but I am unable to find the two year data from any of the phase 3 vaccine trials.
>
> Can you please supply me with the reports on the first two years of phase 3 trials. I am particularly interested in deaths and serious adverse events in vaccinated and placebo groups.
>
> Can you supply the reports on Pfizer, Astrazeneca and Moderna and Novavax 2 year phase 3 vaccine trials or point me to where these results can be obtained?"

Comirnaty (Pfizer)

For this vaccine, the requested information is not held.

By way of background, a marketing authorisation was granted for the Pfizer/BioNTech vaccine (Comirnaty) following a European Commission (EC) decision on 21 December 2020 (PLGB 53632/0002). Further information is available on the European Medicines Agency (EMA) website, a link to this is provided below:

https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty

As described in the published study (C4591001), “The trial is ongoing, and a follow-up duration of 2 years is planned, with possible changes to the trial design to allow participant retention and ongoing data collection”.

Recently, this study has been terminated this is as described in the below excerpt from page 34 of the renewal EPAR.

“Considering the vaccination of a large proportion of the control arm patients in study C4591001, which was unavoidable, it is agreed that the continued follow-up would no longer be informative on the safety and efficacy profile of Comirnaty. Thus, the MAH’s justification for early termination of study C4591001 is considered justified.”

As such the requested information is not held for the purposes of the Act.

Moderna (Spikevax)

For this vaccine, the requested information is not held.

By way of background, a marketing authorisation was granted for the Moderna vaccine on 31 March 2021 following an EC Reliance Procedure (PLGB 53720/0002). Further information is available on the MHRA website and the EMA website, links to these are provided below:

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna

https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-moderna

For the purposes of FOI, these data are not held, and excluding unforeseen events, the requested data are expected to be submitted by 30 June 2023. Please note, in due course these data are expected to be published in a scientific journal, and the clinical study report will be published on the EMA clinical data repository in line with their publication scheme.

Novavax (Product name: Nuvaxovid)

For this vaccine, the requested information is not held.

By way of background, a Marketing Authorisation for Nuvaxovid dispersion for injection was granted in Great Britain (GB, consisting of England, Scotland and Wales) on 3 February 2022 (PLGB 54180/0002).

A link to the public assessment report for Nuvaxovid is below, and according to the document the data for Pivotal study 2019nCoV-302 should be submitted as soon as these data are available, and according to our records this has not yet occurred
Public Assessment Report (publishing.service.gov.uk)

Oxford/AstraZeneca Vaxzevria (AZD1222)

A marketing authorisation was granted for the Oxford/AstraZeneca vaccine on 24 June 2021 following an EC Reliance Procedure (PLGB 17901/0355). Further information is available on the MHRA website and the EMA website, links to these are provided below:

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca
https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca

Section 22 Exemption

For the purposes of the Act these data are held, however, we exempt these data under Section 22 of the FOIA. We expect that these data will be published in due course in the New England Journal of Medicine, and the Clinical study reports will be published on the EMA clinical data repository in line with their publication scheme. In addition, supportive data and conclusions will be presented in the public assessment report. We do not identify a need in the public interest to separate from the standard sequence of events in terms of publication of these data i.e., the formal submission and publication of the data in a scientific journal, the upload of data by the EMA to their repository, and the updated public assessment report which provides necessary context and analysis.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre
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